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PATENT APPLICATION
Attorney's Docket No.: KIR96-01



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Michael J. Elliott, Ravinder N. Maini and Marc Feldmann

Application No.: 08/602,272 Group: 1806

Filed: February 16, 1996 Examiner: N. Johnson

For: METHODS OF PREVENTING OR TREATING CARDIOVASCULAR, CEREBROVASCULAR AND THROMBOTIC DISORDERS WITH TUMOR NECROSIS FACTOR ANTAGONISTS

CERTIFICATE OF MAILING

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PETITION UNDER 37 C.F.R. § 1.144

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

On December 17, 1996, Applicants submitted a Response to Restriction Requirement requesting withdrawal of a restriction requirement in the above-identified patent application. On March 25, 1997, that request was denied and the restriction requirement was made final by the Examiner. Applicants hereby

petition to obtain review of the Examiner's decision to maintain the restriction requirement.

The facts are as follows:

In the Office Action dated November 21, 1996, a restriction requirement was set forth stating four groups. Group I was directed to methods for treating or preventing a cardiovascular disorder and included Claims 1-3. Group II was directed to methods for treating or preventing a cerebrovascular disorder and included Claims 4-5. Group III was directed to methods of treating or preventing a thrombotic disorder and included Claims 6-28. Group IV was directed to methods of decreasing plasma fibrinogen in an individual and included Claims 29-50.

The Examiner stated that restriction was proper in the subject application because (1) the invention of Group I, II, III and IV are distinct as shown by the different method objectives, method steps and parameters and reagents used; (2) the inventions of each group have acquired a separate status in the art as shown by "the different classification and recognized divergent subject matter"; and (3) the searches required for the different groups are not co-extensive.

On December 17, 1996, Applicants submitted a Response to Restriction Requirement in which they provisionally elected to prosecute the claims of Group III and presented arguments to traverse the restriction requirement. Each of Applicants' arguments was made specifically in response to each of the Examiner's points as set forth above.

Regarding point (1), Applicants stated in the response that the inventions of Groups I, II, III and IV are related because the disease states are all associated with disorders relating to the circulatory system and the underlying mechanisms for the inventions are overlapping. For example, it is known that fibrinogen and platelets play integral roles in the formation of blood clots and that elevated circulating fibrinogen and platelet levels are associated with increased risk of developing a blood clotting disorder. In fact, the invention of Group III (treating

or preventing thrombotic disorders) includes embodiments that are also embraced by the inventions of Groups I, II and IV.

Thus, the Examiner's assertion is factually incorrect. The claims presented in elected Group III embrace the treatment of diseases employing the same active ingredients embraced in Groups I, II and IV. This fact is exemplified by dependent Claims 2, 5 and 7, and in Applicants' specification at pages 4-5. Thus, the claims presented in Groups I-IV embrace embodiments with the same method objectives (e.g., the treatment of the same disease states by decreasing fibrinogen levels and, thereby, decreasing thrombosis) by employing the same method steps (e.g., by administering to a patient in need of the treatment) using the same parameters and reagents (e.g., an effective amount of a TNF antagonist).

Regarding point (2), Applicants countered that the domestic and international classifications for each invention are the same. In fact, class 424, subclass 130.1 is indicated by the Examiner to be the classification for each invention (see Office Action dated November 21, 1996 at page 2). Thus, the Examiner's second point is factually incorrect. Further, the Examiner has not shown that the subject matter is "divergent". As set forth above, the subject matter of Groups I-IV is not divergent, but is overlapping.

Regarding point (3), Applicants responded that the searches required for each invention would not place an undue burden upon the PTO. That is, a search of the prior art for the methods defined in one group would also identify prior art that is applicable to the other groups. Furthermore, a complete search, including a literature search, of one invention would necessarily entail a search of the remaining inventions in light of the close and, at times, overlapping relationship of each invention. For example, a search of the prior art for methods of treating or preventing a thrombotic disorder by administering a tumor necrosis factor antagonist (Group III) would necessarily identify prior art that is applicable to Groups I, II and IV.

In the Office Action dated March 25, 1997, the Examiner maintained the restriction requirement, stating that Applicants have pointed to no errors in the restriction requirement. Applicants disagree with this assertion as is clear from the above discussion.

The Examiner also stated that:

> As to the question of burden of search, classification of subject matter is merely one indication of the burdensome nature of the search involved. The literature search, particularly relevant in this art, is not co-extensive and is much more important in evaluating the burden of search. Clearly different searches and issues are involved in the examination of each group.

The reasoning in support of these conclusions has not been provided. Indeed, the only factual basis for this assertion in the original restriction requirement was the U.S. classification system, shown above to be the same for each group. For the reasons set forth above, it is believed that the literature search is also the same.

For the foregoing reasons, it is submitted that the Examiner erred in making and maintaining the restriction requirement, and reversal is respectfully requested. Consideration of the pending claims, in particular, amended Claims 29-50, is respectfully requested.

Respectfully submitted,

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